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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,848	01/18/2002	Norman G. Anderson	2315-148	3044
6449	7590 07/01/2004		EXAMINER	
ROTHWEL 1425 K STR	L, FIGG, ERNST & MA	LU, FRANK WEI MIN		
SUITE 800	EEI, N.W.		ART UNIT	PAPER NUMBER
WASHINGT	ON, DC 20005		1634	
			DATE MAILED: 07/01/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.



Office Action Summary

Application No.	Applicant(s)	
10/050,848	ANDERSON ET AL.	
Examiner	Art Unit	
Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).
Status
 Responsive to communication(s) filed on <u>01 March 2004</u>. This action is FINAL. 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.
Disposition of Claims
 4) Claim(s) 18-25,30 and 32 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 18-25,30 and 32 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.
Application Papers
 9) ☐ The specification is objected to by the Examiner. 10) ☑ The drawing(s) filed on 1/18/2002 (original) is/are: a) ☑ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.
Priority under 35 U.S.C. § 119
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.
Attachment(s)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

4) Interview Summary (PTO-413)

Paper No(s)/Mail Date. __

6) Other:

Notice of Informal Patent Application (PTO-152)

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on March 1, 2004 has been entered. The claims pending in this application are claims 18-25, 30, and 32.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 18-22, 25, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al., (US Patent No. 4,624, 835, published on November 25, 1986).

Davis et al., teach microcentrifugation tube for the concentration of samples for electron microscope.

Regarding claim 18, since Figure 5 taught by Davis et al., (see attached Figure 5 with the examiner's handwritings) teach a centrifuge tube 10 comprising an upper region, a middle region and a low region wherein an inner diameter of said upper region is larger than an inner diameter of said lower region, wherein said upper region is separated from said lower region by said middle region having at least one portion with parallel inner sides and an overall decreasing diameter from said upper region toward said lower region and wherein said lower region has parallel inner sides and a closed bottom, claim 18 is anticipated by Davis et al..

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Regarding claim 19, according to the dictionary, "serrate" means "notched or toothed" (see the attached dictionary in previous office action), since Davis et al., teach that another alternative embodiment of the centrifuge tube 10, score 16, includes a notch (see Figures 1 and 2, lines 65-68 in column 3, and lines 1-3 in column 4), claim 19 is anticipated by Davis *et al.*.

Regarding claims 20 and 25, the claims are drawn to the tubes of claim 18 wherein said lower region has an inner diameter small enough to trap an air bubble between two layers of liquid such that the air bubble will keep said two layers of liquid separate so long as said centrifuge tube is at rest as recited in claim 20 or wherein said tube is prepared from materials such that said tube can be centrifuged at velocities high enough to band viruses in CsC1 gradients without said tube breaking as recited in claim 25. Claims 20 and 25 only recite two functions of the centrifuge tube recited in claim 18. It is known that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987) and while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (see MPEP 2114). Since Davis et al., teach all structure limitations recited in claims 18, 20, and 25, claims 20 and 25 are anticipated by Davis et al..

Regarding claim 21, Davis *et al.*, teach that the width of the bases 36 and 38 of the trapezoidal horizontal cross-section in tip section 30 are approximately 0.25 millimeters and 0.12 millimeters respectively (see column 4, lines 42-51). As shown in Figures 3 and 4, the tip

section 30 and the width of the base 38 of the trapezoidal horizontal cross-section in tip section 30 are located on the lower region of the centrifuge tube wherein the width of the base 38 of the trapezoidal horizontal cross-section in tip section 30 is one of inner diameters of said lower region of the centrifuge tube. Since the width of the base 38 of the trapezoidal horizontal cross-section in tip section 30 (ie., one of inner diameters of said lower region of the centrifuge tube) is 0.12 mm and it is known that 1 inch equals to 25 mm, one of inner diameter of said lower region of the centrifuge tube taught by Davis *et al.*, is 0.0048 inch (0.12/25), which is smaller than 0.25 inch as recited in claim 21.

Regarding claim 22, since Figure 5 with the examiner's handwritings shows that said lower region is at least 5% of the total length of said tube, claim 22 is anticipated by Davis et al...

Regarding claim 32, since Figure 5 shows that the upper region of the centrifuge tube taught by Davis *et al.*, has an outer diameter larger than an outer diameter of the lower region of the centrifuge tube (see attached Figure 5 with the examiner's handwritings), claim 32 is anticipated by Davis *et al.*.

Therefore, Davis et al., teach all limitations recited in claims 18-22, 25, and 32.

Response to Arguments

In page 6, third and fourth paragraphs of applicant's remarks, applicant argues that: (1) Davis *et al.*, do not teach that the lower region has parallel sides as recited in amended claim 18; and (2) "[T]he only parallel region in Davis et al., is the 'gripping region 40' shown in Figure 5. Since this region is for gripping the centrifuge tube for slicing the lower section, the parallel region can not be considered as a 'low region'. Therefore, Davis et al., does not disclose and cannot suggest the present invention ".

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This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. First, as shown in Figure 5 (see attached Figure 5 with the examiner's handwriting), Davis *et al.*, do teach that the lower region has parallel sides as recited in amended claim 18 wherein the part of gripping region 40 is parallel sides in the lower region of the ultracentrifuge tube. Second, since claim 18 does not indicate, in the ultracentrifuge tube, where is a separate point of the middle region and the lower region, the part of gripping region 40 containing the parallel region is considered as the part of the lower region of the ultracentrifuge tube.

II. In page 6, last paragraph bridging to page 7, first paragraph of applicant's remarks, applicant argues that "[D]avis does not teach a middle region having one or more serrations as claimed in claim 19. The middle region is smooth in all of the figures. While the examiner asserts that the 'score' in Figure 1 is a serration, this is not consistent with the teaching of Davis. Davis mentions having a score on the external surface of the tube 'to accommodate the separation of the tube 10 during the removal of the tube 10 from a completed sample' (column 4, lines 1-3). There is no suggestion that the score extends to the inside of the tube. As such, a serration is not present and thus the reference docs not support the rejection".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. According to the dictionary, "serrate" means "notched or toothed". Although applicant argues that the score (including a notch) does not extend to the inside of the tube, claim 19 does not require that one or more serrations locate in the inside of the tube. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

III. In page 7, second paragraph of applicant's remarks, applicant argues that "claim 20 recites that the lower region has the ability to trap an air bubble between two liquids of liquid. The lower section of Davis is angled and is very unlikely to be able to hold an air bubble because the tube sides are not on the sides or top of the air bubble to prevent it from rising by friction. Accordingly, for all of these rejections, the rejection should be withdrawn".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. First, applicant does not provide evidence to show that the lower region of microcentrifugation tube taught by the Davis et al., can not trap an air bubble between two layers of liquid such that the air bubble will keep said two layers of liquid separate so long as said centrifuge tube is at rest. Second, the limitation "trap an air bubble between two layers of liquid such that the air bubble will keep said two layers of liquid separate so long as said centrifuge tube is at rest" recited in claim 20 is not a structural limitation of the centrifuge tube but a functional limitation of the centrifuge tube recited in claim 18. It is known that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987) and while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (see MPEP 2114). Since Davis et al., teach all structural limitations recited in claim 20, claim 20 is anticipated by Davis et al..

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis *et al.*, as applied to claims 18-22, 25, and 32 above, and further in view of Simmonds *et al.*, (US Patent No. 4,260,873, published on April 7, 1981).

The teachings of Davis et al., have been summarized previously, supra.

Davis et al., do not disclose that the inner surfaces of a centrifuge tube are polished by vapor polishing agent as recited in claim 23.

Simmonds does teach to polish the inner surfaces of a centrifuge tube using vapor polishing agent (see columns 1 and 2).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made an ultracentrifuge tube wherein its inner surface

are polished by vapor polishing agent in view of the patents of Davis *et al.*, and Simmonds. One having ordinary skill in the art would have been motivated to do so because vapor polishing would remove oxidized plastic, dissolve uncovered plastic in a centrifuge tube, and make a smooth inner surface for the centrifuge tube (see Simmonds *et al.*, column 1, lines 14-28). One having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success to make an ultracentrifuge tube wherein its inner surface are polished by

Response to Arguments

vapor polishing agent.

In page 7, third paragraph of applicant's remarks, applicant argues that "[W]ithout agreeing with the rejection, it should be noted that Simmonds et al does not correct for the deficiencies in Davis et al in the initial rejection discussed above or alter the teachings of Davis et al to suggest the recitations in claims 18, 19 and 20 argued above. Accordingly, this rejection should also be withdrawn".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. Since Davis *et al.*, teach all limitations recited in claims 18-22, 25, and 32 (see above), the combination of Davis *et al.*, and Simmonds *et al.*, is not used to reject claims 18-20. Since applicant does not argue the combination of Davis *et al.*, and Simmonds *et al.*, the rejection on claim 23 is maintained.

6. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis *et al.*, as applied to claims 18-22, 25, and 32 above, and further in view of Saunders *et al.*, (US Patent No. 5,550,060, published on August 27, 1996).

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The teachings of Davis et al., have been summarized previously, supra.

Davis *et al.*, do not disclose a centrifuge tube whose inner surfaces are coated with an adhering polymer as recited in claim 24.

Saunders *et al.*, do teach to coat the inner surfaces of a centrifuge tube with an adhering polymer (see columns 11 and 12).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made an ultracentrifuge tube wherein the inner surfaces of the centrifuge tube are coated with an adhering polymer in view of the patents of Davis *et al.*, and Saunders *et al.*. One having ordinary skill in the art would have been motivated to do so because, comparing with a centrifuge tube without an inner surface coating, the use of a centrifuge tube having an inner surface coating (ie., an adhering polymer) would improve cell separation result (see Saunders et al., second paragraph in column 6 and claim 1 in column 16). One having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success to coat the inner surfaces of a centrifuge tube with an adhering polymer.

Response to Arguments

In page 7, fourth paragraph of applicant's remarks, applicant argues that "[W]ithout agreeing with the rejection, it should be noted that Sanders et al does not correct for the deficiencies in Davis et al in the initial rejection discussed above or alter the teachings of Davis et al to suggest the recitations in claims 18, 19 and 20 argued above. Accordingly, this rejection should also be withdrawn".

This argument has been fully considered but it is not persuasive toward the withdrawal

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of the rejection. Since Davis *et al.*, teach all limitations recited in claims 18-22, 25, and 32 (see above), the combination of Davis *et al.*, and Saunders *et al.*, is not used to reject claims 18-20. Since applicant does not argue the combination of Davis *et al.*, and Sanders *et al.*, the rejection on claim 24 is maintained.

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis *et al.*, as applied to claims 18-22, 25, and 32 above, and further in view of Finney *et al.*, (US Patent No.4,358,425, published on November 9, 1982).

The teachings of Davis et al., have been summarized previously, supra.

Davis *et al.*, do not disclose a centrifuge tube made by polycarbonate as recited in claim 30.

Finney *et al.*, teach a centrifuge tube made by polycarbonate or polysulfone (see column 2, last paragraph).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made a centrifuge tube using polycarbonate in view of the patents of Davis *et al.*, and Finney *et al.*. One having ordinary skill in the art would have been motivated to do so because a centrifuge tube made by polycarbonate would provide a relatively think walled, rigid, transparent tube that can be autoclaved (see Finney *et al.*, column 2, last paragraph). Furthermore, it is a routine practice for one having ordinary skill in the art to make a centrifuge tubes using a plastic material such as polycarbonate since Finney *et al.*, has taught a centrifuge made by polycarbonate. One having ordinary skill in the art at the time the

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invention was made would have a reasonable expectation of success to make a centrifuge tubes using polycarbonate.

Response to Arguments

In page 7, fifth paragraph of applicant's remarks, applicant argues that "[W]ithout agreeing with the rejection, it should be noted that Finney et al does not correct for the deficiencies in Davis et al in the initial rejection discussed above or alter the teachings of Davis et al to suggest the recitations in claims 18, 19 and 20 argued above. Accordingly, this rejection should also be withdrawn".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. Since Davis *et al.*, teach all limitations recited in claims 18-22, 25, and 32 (see above), the combination of Davis *et al.*, and Finney *et al.*, is not used to reject claims 18-20. Since applicant does not argue the combination of Davis *et al.*, and Finney *et al.*, the rejection on claim 30 is maintained.

Conclusion

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing

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date of this final action.

9. No claim is allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile

transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notices published in the Official

Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG

94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703)872-

9306 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be

directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu

PSA

June 25, 2004

RATENT EXAMINER

part of the office action

Must be scanned

Nov. 25, 1986

4,624,835

U.S. Patent

